

### **DETAILED ACTION**

1. This is a FINAL Office Action in response to Applicant's reply of June 22, 2009, which was in reply to a non-final Office Action mailed on December 22, 2008. Claims 1, 11, and 12 have been amended, and no Claims have been added or canceled.

### ***Claim Objections***

- Claim 1 is objected because in Line 1 and in step (f), --prosthesis-- should replace "prosthesis" and --pre-preg(s)-- should replace "prepregs"
- Claim 8 is objected to because it lacks proper antecedent basis for "the intermediate sheet" as recited in Lines 1-2. For the purposes of examination, the Examiner presumes Claim 8 to read, in part "A method as claimed in claim 2 wherein the intermediate sheet is cut..." to further clarify that the intermediate sheet is being cut from the drum at the recited angles rather, as opposed to the pre-pegs being cut at the recited angles, a modification which the Examiner believes is Applicant's intended meaning for Claim 8 since the cutting in Claim 8 is recited to happen before the pre-preg is even formed. Additionally, there is no proper antecedent basis for "the final sheet" in Line 3 of Claim 8; the Examiner presumes it to refer to the sheet produced in step (a).
- Claim 12 is objected to because it should currently read --weight categories of the patients-- and not "weight categories **of of** the patients"
- Appropriate correction is required.

***Claim Rejections - 35 USC § 103***

2. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

3. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
  2. Ascertaining the differences between the prior art and the claims at issue.
  3. Resolving the level of ordinary skill in the pertinent art.
  4. Considering objective evidence present in the application indicating obviousness or nonobviousness.
4. Claims 1, 4-9, and 11-12 are rejected under 35 U.S.C. 103(a) as being unpatentable over Moran et al. (US 5,522,904 A, hereinafter Moran) in view of Socci et al. (US 6,851,463 B1, hereinafter Socci).
5. Regarding Claim 1, Moran teaches a method of construction of a prosthesis for patients of various weight categories, said method including the steps of:
- a) impregnating non-metallic fibers in a thermosetting resin whereby said impregnated fibers are wound onto a drum so as to provide an intermediate composite sheet formed of the fibers, then cutting the sheet while it is supported on the drum to remove the sheet and form pre-pregs having fibers oriented at two relatively different angles (Column 6 Lines 33-48);

- b) stacking the pre-pregs having fibers oriented at two relatively different angles to form a thick sheet/stack of pre-pregs wherein each pair of adjacent pre-pregs define a double layer of fibers in different planes with the fibers in each adjacent layer having a different angle of orientation to a longitudinal axis of the pre-peg stack  
(Column 6 Lines 49-58 and Figure 2)
- c) cutting a plurality of pre-pregs from said sheet formed in step (b), thereby forming layers of said cut pre-pregs  
(Column 5 Lines 10-12 disclose that a plurality of shaped pre-pregs may be cut from the sheet/stack in step (b) prior to heating);
- d) taking the layers of said pre-pregs obtained from step (c) so that said layers are arranged in stacked relationship in a mold cavity of a compression mold  
(Column 6 Lines 59-61, wherein in the case of cutting the pre-pregs prior to molding as applied immediately above, the stack of coupons being placed in the mold would be the cut/shaped pre-pregs);
- e) compression molding at elevated temperature (also see Column 6 Lines 59-61); and
- f) removing the prosthesis from the compression mold (inherent in order to perform the post-processing described in Column 6 Lines 65-67, as well to use to the prosthesis as Moran clearly intends). .

However, Moran does not teach folding a sheet directly back on itself by bending adjoining parts of the sheet along adjacent fold lines, the fold lines arranged at an angle that is not perpendicular or parallel to the fibers, so that said fibers are arranged in an

intersecting orientation to form a pre-peg having a double layer of fibers in different planes with the fibers in each adjacent layer having a different angle of orientation to a longitudinal axis of the pre-peg.

In analogous art pertaining to fiber-reinforcement, Socci teaches folding sheets in such a manner (see Figures 7a-7f for a non-limiting example) for the benefit of forming a folded composite sufficient to serve a given utility so that edges of the folded sheet do not have free ends at the outer edge thereof to thereby provide a stronger finished product (as per Column 10 Line 62 – Column 11 Line 18).

Therefore, it would have been obvious to a person having ordinary skill in the art at the time of the invention to apply Socci to Moran for the benefit of forming a folded composite that allows replacing Moran's step of stacking pairs of pre-pregs with a step as per Socci wherein single pre-pregs are folded to serve the equivalent function as the stacked pairs so that at least some edges of the cut pre-pregs do not have free ends at the outer edge thereof to thereby provide a stronger finished product

Additionally, the Examiner characterizes the hypothetical cut pre-pregs obtained from the folded pre-pregs as follows: While still connected at some edges, the bottom and top pre-peg of each folded layer that has been cut are broadly considered separate pre-pregs, wherein the bottom pre-peg is considered to be a pre-peg comprising fibers having an intersecting orientation, and the top pre-peg is considered a pre-peg comprising fibers having a longitudinal orientation.

6. Regarding Claims 4-7, the relative configuration of pre-pregs in Figure 2 of Moran would be maintained in the hypothetical combination applied above, thereby comprising an alternating lay-up sequence of intersecting fiber orientation with longitudinal fiber orientation as claimed.
7. Regarding Claims 8-9, since the angles claimed therein are not expressed in relation to a fixed axis, Moran's teaching of cutting rectangles impregnated fibers at a nominal angle of 40° (as applied above and carried through to the hypothetical combination) would also comprise cutting the sheet at a variety of different angles selected from the group comprising 30° and 45° so that the sheet of step (a) has sloping slides having an acute angle to vertical before folding of the final sheet upon itself to form said pre-preg.
8. Regarding Claim 11, Moran teaches in Column 6 Lines 46-48 that pre- pegs having fibers arranged in a latitudinal and/or longitudinal orientation are formed from an intermediate sheet which is cut at an angle of 0° for longitudinal fibers having regard to a longitudinal axis of a drum supporting the intermediate sheet, and thus the Examiners that the skilled artisan making the hypothetical would have maintained that angle of cutting for the top (longitudinal) pre-preg layers in the hypothetical combination.
9. Regarding Claim 12, since Moran does not positively disclose that differently-sized compression molds are required for patients of different weight categories, it must

be presumed that step (d) is carried out in a mold cavity having the same dimensions regardless of the different weight categories of the patients.

10. Claim 2 is rejected under 35 U.S.C. 103(a) as being unpatentable over Moran in view of Socci as applied to Claim 1 above, and further in view of Oosedo et al. (US 2002/0007022, hereinafter Oosedo).

11. Regarding Claim 2, the previous combination teaches the general method as applied above, but does not teach that sheet of release paper on the drum supports the impregnated fibers.

In analogous art pertaining to fiber reinforcement, Oosedo teaches that impregnated fibers are supported by release paper (Figure 2 Item 5 as per [0019]) on a drum for the benefit of providing easy release of impregnated fibers.

Therefore, it would have been obvious to a person having ordinary skill in the art at the time of the invention to apply release paper as per Oosedo to the previous combination for the benefit of providing easy release of impregnated fibers.

12. Claim 3 is rejected under 35 U.S.C. 103(a) as being unpatentable over Moran in view of Socci as applied to Claim 1 above, further in view of Chang et al. (US 5,192,330, hereinafter Chang) as applied to Claim 1 above, and still further in view of Koizumi.

13. Regarding Claim 3, the previous combination teaches the general method as applied above, but does not teach a hot-melt technique.

In analogous art pertaining to fiber-reinforcement, Chang teaches a known hot melt technique that yields a predictable result of a pre-preg sheet wherein, after hot melt resin impregnation of the fibers, the fibers are laid into a continuous sheet (Column 5 Line 68 - Column 6 Line 4).

Therefore, it would have been obvious to a person having ordinary skill in the art at the time of the invention to use the known hot-melt technique of Chang to yield the predictable result of pre-preg sheet in the hypothetical combination.

However, this hypothetical combination does not teach that the sheet is laid onto a sheet of release paper of that the sheet is subsequently stored as rolls.

In analogous art pertaining to pre-preg production, Koizumi teach the use of release paper and storing the sheet as a roll ("wound by the second winder" Abstract) for the benefit of preventing pre-preg layers from sticking together thus making for a faster process and storing the sheets in a manner that does not compromise strength of the sheets, thus making for a stronger product.

Therefore, it would have been obvious to a person having ordinary skill in the art at the time of the invention to apply Koizumi to the previous combination for the benefit of preventing pre-preg layers from sticking together thus making for a faster process and storing the sheets in a manner that does not compromise strength of the sheets, thus making for a stronger product.

14. Claim 10 is rejected under 35 U.S.C. 103(a) as being unpatentable over Moran in view of Socci in further view of Oosedo, as applied to Claim 2 above, and still further in view of Chang.

15. Regarding Claim 10, Oosedo further teaches that cutting of pre-pregs is carried out by provision of cutting lines situated at an angle corresponding to desired angles of cutting (Figure 2 Item 8 and [0019]) for the benefit of ensuring the cuts are as accurate as possible by providing the cutting lines or grooves as guides for the cutting process, thus making the process more economically efficient by conserving material., but the previous combination does not expressly teach that intersecting fiber angles for the pre-pregs are selected from the group consisting of 15°, 22.5°, 30°, 45°, and 60°, or that cut lines should be formed on the outer surface of the drum to allow the intermediate sheet to be cut at angles to produce the claimed intersecting fiber angles.

In analogous art pertaining to fiber reinforcement, Chang teaches that intersecting fiber angles for the pre-pregs are selected from the group consisting of 15°, 22.5°, 30°, 45°, and 60° for the benefit of providing optimum reinforcement in a prosthesis (as per Column 5 Lines 18-30).

Therefore, it would have been obvious to a person having ordinary skill in the art at the time of the invention to apply Chang to the previous combination for the benefit of providing optimum reinforcement in a prosthesis while ensuring the cuts are as accurate as possible by providing the cutting lines or grooves as guides for the cutting process, thus making the process more economically efficient by conserving material.



***Response to Arguments***

16. Applicant's arguments with respect to claims 1-12 have been considered but are moot in view of the new ground(s) of rejection.

***Conclusion***

17. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

18. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

19. Any inquiry concerning this communication or earlier communications from the examiner should be directed to RYAN OCHYLSKI whose telephone number is 571-270-

7009. The examiner can normally be reached on Monday through Thursday and every other Friday from 9:00-6:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Joseph Del Sole can be reached on 571-272-1130. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

rmo

/Joseph S. Del Sole/  
Supervisory Patent Examiner, Art Unit 1791